PHARMACY GUILD OF NEW ZEALAND

1 October 2025

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

Sent via email to: *consult@pharmac.govt.nz*

Dear Sir/Madam,

Re: Proposal to fund a new brand of methylphenidate hydrochloride

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation and the largest representative of community pharmacy owners in New Zealand. We provide leadership on all issues affecting the sector and advocate for the business and professional interests of community pharmacy.

This submission focuses on Guild members' concerns around general economic, funding, access, and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, medicine safety, efficacy, or appropriateness for individual patients.

The Guild strongly supports the proposal to fund another brand of methylphenidate extended-release, Methylphenidate Sandoz XR, supplied by Sandoz, for people with attention deficit hyperactivity disorder (ADHD) and narcolepsy from 1 December 2025. The recent shortages of various formulations of methylphenidate have created considerable challenges for prescribers, pharmacists, and patients in maintaining consistent ADHD treatment. These shortages have resulted in delays and interruptions in care and treatment continuity, which are particularly harmful when managing a chronic condition like ADHD, leading to significant distress for patients and their whānau and negatively affecting quality of life.

1. Current pressures on the medicine supply chain for the treatment of ADHD

We believe that the funding of Methylphenidate Sandoz XR will play a critical role in alleviating the current pressure on the medicine supply chain for the treatment of ADHD and reduce the burden on healthcare providers, particularly pharmacists, who continue to manage persistent stock shortages of extended-release methylphenidate products, supporting continuity of care for patients. It will further strengthen preparedness for the upcoming changes in February 2026, when general practitioners and nurse practitioners will be able to prescribe ADHD medicines.

Whilst acknowledging this positive step, we seek clarification on the strategies Pharmac plans to implement to ensure a consistent and reliable national supply of Methylphenidate Sandoz XR to community pharmacies across the country. Equitable distribution will be essential to guarantee fair access to all brands and formulations of methylphenidate, regardless of a patient's location or the size of their local community pharmacy, and we recommend that Pharmac:

- Maintain transparent and timely communication regarding stock availability, allocation strategies, and contingency plans to prevent regional disparities and support healthcare providers in managing patient expectations.
- Engage proactively with wholesalers, suppliers and the wider health sector to enable early detection and response to supply pressures.

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- Consider strategies such as stockpiling, strengthened allocation processes, and targeted distribution measures to prevent regional disparities.

2. Clinical information and brand substitution of methylphenidate modified-release/extended-release tablets

The proposal notes that Methylphenidate Sandoz XR is the generic version of Concerta ER (a methylphenidate extended-release tablet), which is already funded by Pharmac. However, there is conflicting guidance currently available on the Pharmac website, including:

- Medsafe's 2023 guidance (available here) recommending caution when switching between long-acting methylphenidate products due to formulation differences.
- Clinical advice obtained by Pharmac for prescribers (available here) stating "*the Medsafe datasheets for Concerta ER and Methylphenidate ER (Teva) indicate the same pharmacokinetic profile, but clinicians and patients have reported experiencing different release profiles, thus dosing may need to be adjusted on a case-by-case basis*".
- Under the 'Advice for pharmacists' section, available here, providing inconsistent advice for pharmacists regarding substituting between brands of methylphenidate ER (Concerta ER and Teva ER), particularly around whether a new prescription is require depending on whether the medicine is written generically or by brand.

Further complicating matters, current prescriber patient management systems (PMS) have been programmed to prevent the generic prescribing of methylphenidate. When prescribers attempt to prescribe "methylphenidate extended-release tablets", the PMS system generates prescriptions specifying a particular brand (either Concerta ER or Teva ER), creating unnecessary barriers to brand flexibility, despite prescribers being encouraged to prescribe generically to mitigate the need for new prescriptions when stock of one brand is unavailable.

Given these inconsistencies, there is an urgent need for Pharmac to restore and strengthen confidence in their advice by providing clear, consistent, and up-to-date guidance, along with regulatory rules, on whether methylphenidate extended-release tablets can be generically substituted. This should include:

- Explicit guidance for prescribers and pharmacists on managing transitions between brands of methylphenidate to minimise errors and confusion, particularly with the potential funding of another methylphenidate extended-release brand.
- Practical resources, such as quick-reference comparison tables, cross-brand equivalence notes, and dispensing protocols to support therapeutic continuity when patients are switched between brands, especially in situations where supply issues necessitate change.
- Provision of clear information for patients and ADHD advocacy groups, ensuring they are informed about potential brand changes, what this means for their treatment, and how continuity of care will be maintained.

3. Special authority criteria

While the proposal states that Methylphenidate Sandoz XR will share the same Special Authority criteria as Ritalin, Rubifen, Rubifen SR, and Methylphenidate ER – Teva, it is also described as a generic version of Concerta ER, which, despite having similar formulation and release properties, still requires a separate Special Authority with different criteria. This inconsistency creates unnecessary administrative burden and confusion, and we seek clarity on why Methylphenidate Sandoz XR requires a separate Special Authority application to its generic, Concerta ER.

Despite the removal of renewal criteria in November 2024, pharmacists still continue to face significant burden due to the requirement for different Special Authority numbers across the

various brands of methylphenidate. Pharmacists are frequently required to contact prescribers to resolve discrepancies, obtain the correct Special Authority, or request the prescriber apply for the alternative formulation or new ADHD stimulant, diverting valuable time and resources away from direct patient care. These administrative hurdles not only increase the workload for pharmacy staff but also contribute to unnecessary delays in treatment, impacting patients who rely on timely and consistent access to medicines to manage their chronic condition effectively, disrupting a patient's ability to function optimally in their daily lives, and creating frustration and eroding trust in the healthcare system.

We strongly recommend that Pharmac streamline the Special Authority application process by:

- Standardising the approval criteria across all methylphenidate formulations, enabling pharmacists to dispense the available brand without requiring additional interventions from prescribers, minimising unnecessary treatment delays, and significantly easing the administrative burden on both community pharmacies and prescribers.
- Implementing integrated digital solutions that automate and streamline the application and validation of Special Authority approvals, such as a digital platform for tracking and verifying Special Authority applications that is accessible to pharmacists to quickly access and submit correct details whilst minimising communication with prescribers, and the introduction of real-time validation within prescriber PMS systems that could proactively identify and flag errors before prescriptions are sent to pharmacies.

By simplifying these procedures and implementing solutions to improve prescription accuracy and enhance workflow efficiency, pharmacists could devote more time to patient care, rather than being overwhelmed by unnecessary paperwork and frequent prescription adjustments and, more importantly, patients would receive timely and consistent access to their ADHD medicines without avoidable delays or errors.

We thank Pharmac for the opportunity to provide feedback on this proposal. While we support the funding of Methylphenidate Sandoz XR as an important step toward strengthening supply resilience and improving access to ADHD treatments, we urge Pharmac to ensure that the funding of Methylphenidate Sandoz XR is not undermined by avoidable administrative and supply barriers, as without these changes, the intended benefits for prescribers, pharmacists and more importantly, patients may be significantly diluted. We remain committed to working constructively with Pharmac and sector organisations to support solutions that enhance continuity of treatment and improve outcomes for people living with ADHD.

If you have any questions about our response, please contact our Senior Advisory Pharmacists, Martin Lowis (martin@pgnz.org.nz, 04 802 8218) or Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services